Conformance Review Checklist – Part 1

APPL_TYPE __; APPL_NO _____; IN_DOC_TYPE _____; SEQ_NO ____; STAMP_DATE _____

Physical Review: Check the jacket and accompanying paper

Preparation
- Blue Archival Jacket w/label
- Jacket and disk pockets bar coded

Media –
- 3.5 inch DOS formatted floppy disks (maximum 10)
- ISO 9660 CD-ROMs (maximum 5)
- DEC DLT 20/40 or 10/20 GB format using OPENVMS with VMS backup
- DEC DLT 20/40 or 10/20 GB format using NT server 4.0 with NT backup

Paper Copy
- Description of submission
- Table of Contents including any electronic portion
- Description of any deviation from Guidance Instructions
- File listing or directory of electronic media *(Information only)*
- Instructions for handling electronic media *(Information only)*

Media Label
- NDA/IND number
- Proprietary and Generic Name
- Company Name
- Submission serial number, if applicable
- Date: DD-MMM-YYYY
- Disk Number

Sections Included
- Section 1: Comprehensive Table of Contents
- Section 11: Case Report Tabulations
- Section 12: Case Report Forms
- **No other sections are included.**

Report: _____

Recommendations: _____

_____

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If any problems appear, immediately contact the SCSO/Project Manager, the EDR Project Officer and others on the *EDR Distribution List by e-mail.*

Conformance Review Checklist - Part 2

APPL_TYPE __; APPL_NO _____; IN_DOC_TYPE _____; SEQ_NO ____; STAMP_DATE _____

Electronic Review: Media readability

3.5 inch disk -

START => PROGRAMS => ACCESSORIES => SYSTEM TOOLS => SCANDISK
Standard scan + DO NOT AUTOMATICALLY FIX ERRORS => START

- **Report:** ScanDisk did not find any errors on this drive.

CD-ROM –

[click] MY COMPUTER => [right click] CD-ROM => [click] PROPERTIES

- **Report:** Label, type and space used should be reported

DLT Tape –

Read directory

$ ALLO MKB500:=>MOUNT MKB500: =>BACKUP/LIST/REWIND MKB500: /SAVE_SET

- **Report:** Full directory legible

Report: _____

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Recommendations: _____

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If any problems appear, immediately contact the SCSO/Project Manager, the EDR Project Officer and others on the *EDR Distribution List* by e-mail.

Conformance Review Checklist – Part 3

General Requirements

Inspect the Directory:

- NDA number for primary directory
- Subdirectory for each application subsection
- Subdirectory for full text indexes: *Indexes*
- ISO standard 8.3 filenames with no punctuation
- Files should not be compressed

Required files
- Copy of the cover letter in pdf format: ***cover.pdf***
- Table of contents for the submission in pdf format: ***index.pdf***

Acrobat pdf Requirements

Examine the Document Info fields as files are examined
Document Information – General
- Title: *See the Guidance for each specific document*
- Subject: N plus 6 digit number, brand name, generic name
- Author: (optional) Sponsor of submission
- Keywords: *See the Guidance for each specific document*

Document Info – Open
- Open dialog: Bookmarks and Page, or if no bookmarks, page only. Magnification and layout to default.

Document Info – Security
- Security: Do not password protect pdf files

Document Info – Indexing
- If an index exists, the complete filename of the index should be specified

Report: _____

_____

Recommendations: _____

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Conformance Review Checklist – Part 4

APPL_TYPE __; APPL_NO _____; IN_DOC_TYPE _____; SEQ_NO ____; STAMP_DATE _____

A. NDA Subsection 1 – Index (NDA Table of Contents)

Organization of Files

- Comprehensive index as a single pdf file: *index.pdf*

Document Identification

- Document Info Title field: *NDA Table of Contents*

Table of Contents

List all sections of the NDA

- Paper: List volume(s) and page numbers
- Electronic: Volume and location of files by directory with hypertext link to Corresponding Table of contents for each section.

Hypertext Linking

- Bookmarks to each section ***Table of Contents***
- Hypertext links to each section ***Table of Contents***

No additional linking required

Indexing

None

Additional Guidance

None

Report: _____

_____

Recommendations: _____

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Conformance Review Checklist – Part 4, Cont.

APPL_TYPE __; APPL_NO _____; IN_DOC_TYPE _____; SEQ_NO ____; STAMP_DATE _____

NDA subsection 11 – Case Report Tabulations (CRT):

File Organization

- One pdf file for each complete CRF domain
- One subdirectory for all domains in a study
- One directory for all domains, named ***Domains***

Patient profiles (1)

- One pdf file for each complete patient profile
- One subdirectory for all patient profiles in a study
- One directory for all profiles, named ***Pprofile***

Patient profiles (2)

- One pdf file for all patient profiles in a single study
- One directory for all studies, named ***Pprofile***

Document Identification

Domain Profiles (Patient Line listings)

- Document Info Title Field:
  Domain Profile (dp), study xxx, CRF domain name.
  Ex. for patient 001 in study 2001, for vital signs:
  dp, study 2001, vital signs

Patient profiles

- Document Info Title Field:
  Patient profile form (pp), study xxx, site xx (or investigator xx), patient ID.
  Ex. for patient 001 in study 2001 at site 3:
  pp, study 2001, site 03, patient ID 2001-03-001

Table of Contents

Domain profiles (patient Line Listings)

- Name the Line Listing Table of Contents file: DPTOC.pdf and place in the CRF directory
- Link Domain Profiles table of contents to overall table of contents for the submission.
- Line Listing Table of Contents table of contents
- List all CRF domains by study
- Hypertext link between CRF domains in the Line Listing table of contents and the corresponding CRF domain line listing pdf file.

Patient profiles

- profiles directory
- Link PP table of contents to overall table of contents for the submission.
- Patient Profiles Table of Contents
- List unique patient ID numbers by study
- corresponding patient's patient profile pdf file.

Hypertext linking

Indexing

- Domain Profiles (Patient Line listings) – Use Adobe Catalog
- Patient profiles – Use Adobe Catalog

Report: _____

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Recommendations: _____

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Conformance Review Checklist – Part 4, Cont.

APPL_TYPE __; APPL_NO _____; IN_DOC_TYPE _____; SEQ_NO ____; STAMP_DATE _____

C. NDA Subsection 12 – Case Report Forms (CRF):

Organization of Files

- One directory for all studies, Labeled "*CRF"*
- One subdirectory per study, identified with study number
- One file for each patient

Document Identification

- Document Info Title Field:
  Case report form (crf), study xxx, site xx (or investigator xx), unique patient ID.
  Ex. for patient 001 in study 2001 at site 3:
  crf, study 2001, site 03, PID 2001-03-001

Table of Contents

- Name the CRF table of contents file: CRFTOC.pdf and place in the CRF directory
- CRF table of contents
  List unique patient ID numbers by study
  Hypertext link between patient listings in CRF table of contents and the corresponding patient's CRF pdf file.

Hypertext linking

- Table of contents (page 1) within patient CRF file – bookmark to page location of all CRF domains collected at each study visit
- Bookmark link to each study visit and/or each CRF domain (such as demographics, vital signs, labs, etc.

Indexing (use Adobe Catalog)

- Index all CRFs – Document info, title field data

Additional Guidance:
None

Report: _____

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Recommendations: _____

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Conformance Review Checklist – Part 5

APPL_TYPE __; APPL_NO _____; IN_DOC_TYPE _____; SEQ_NO ____; STAMP_DATE _____

Online Functional Submission Testing

Adobe Acrobat Appearance, Exchange 3.0

- s All materials are legible
- s All Acrobat features are functional

Section 1: Master Table of Contents or Index